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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 786,436	07 16 2001	Hermann Wagner	C1041 7010	1340

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EXAMINER

WHITEMAN, BRIAN A

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 10 02 2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/786,436

Applicant(s)

WAGNER ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 34-171 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 34-171 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other

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### DETAILED ACTION

Claims 34-171 are pending.

#### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 34-60, 61-89, and 90-103, drawn to a composition comprising an oligonucleotide comprising the sequence: N1-N2-G-N3-G and an antigen.

Group II, claims 61-74, drawn to a composition comprising an oligonucleotide comprising the sequence: N1-N2-G-N3-G and an anti-microbial agent.

Group III, claims 61-74, drawn to a composition comprising an oligonucleotide comprising the sequence: N1-N2-G-N3-G and other pharmaceutical agent that is not an antigen or anti-microbial agent.

Group IV, claim(s) 104-116, drawn to a method for treating a subject having a tumor, comprising an oligonucleotide comprising the sequence: N1-N2-G-N3-G.

Group V, claim(s) 117-129, drawn to a method for treating or preventing a bacterial infection, comprising administering to a subject an oligonucleotide comprising the sequence: N1-N2-G-N3-G.

Group VI, claim(s) 117-129, drawn to a method for treating or preventing parasitic infection, comprising administering to a subject an oligonucleotide comprising the sequence N1-N2-G-N3-G.

Group VII, claim(s) 130-141, drawn to a method for treating or preventing spontaneous abortion, comprising administering to a subject an oligonucleotide comprising the sequence N1-N2-G-N3-G.

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Group VIII, claim(s) 142, drawn to a method for activating NK cells comprising: contacting an NK cell with an oligonucleotide comprising the sequence: N1-N2-G-N3-G.

Group IX, claim(s) 143-145, drawn to a method for enhancing cellular uptake of an agent comprising: contacting a cell with an agent conjugated to an oligonucleotide comprising the sequence: N1-N2-G-N3-G.

Group X, claims 146-171, drawn to an oligonucleotide comprising the sequence: N1-N2-G-N3-G.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT rule 13.2, they lack the same or corresponding special features for the following reasons:

37 CFR 1.475(c) states:

“If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.”

37 CFR 1.475(d) also states:

“If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).”

37 CFR 1.475(e) further states:

“The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim.”

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The inventions listed as Groups I-X do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical feature for the following reasons:

The special technical feature of Group I is considered to be a composition comprising an oligonucleotide comprising the sequence: N1-N2-G-N3-G and an antigen.

The special technical feature of Group II drawn to a composition comprising an oligonucleotide comprising the sequence: N1-N2-G-N3-G and an anti-microbial agent.

The special technical feature of Group III drawn to a composition comprising an oligonucleotide comprising the sequence: N1-N2-G-N3-G and a pharmaceutical agent that is not an antigen.

The special technical feature of Group IV to be a method for treating a subject having a tumor, comprising an oligonucleotide comprising the sequence: N1-N2-G-N3-G.

The special technical feature of Group V is considered to be a method for treating or preventing a bacterial, comprising administering to a subject an oligonucleotide comprising the sequence: N1-N2-G-N3-G.

The special technical feature of Group VI is considered to be a method for preventing or treating a parasitic infection, comprising administering to a subject an oligonucleotide comprising the sequence: N1-N2-G-N3-G.

The special technical feature of Group VII is considered to be a method for preventing or treating spontaneous abortion, comprising administering to a subject an oligonucleotide comprising the sequence: N1-N2-G-N3-G.

The special technical feature of Group VIII is considered to be a method for activating NK cells comprising: contacting an NK cell with an oligonucleotide comprising the sequence: N1-N2-G-N3-G.

The special technical feature of Group IX is considered to be a method for enhancing cellular uptake of an agent comprising: contacting a cell with an agent conjugated to an oligonucleotide comprising the sequence: N1-N2-G-N3-G.

The special technical feature of Group X is considered to be drawn to an oligonucleotide comprising the sequence: N1-N2-G-N3-G by itself or with a pharmaceutically acceptable carrier.

The technical feature linking Groups I-X appear to be that they all relate to a G-motif oligonucleotide sequence designated as N1-N2-G-N3-G.

However, Burgess et al. (PNAS, Vol. 92:4051-4055, 1995) teaches the oligonucleotide sequence GTACACATGGGGGAGT.

Therefore, the technical feature linking the inventions of groups I-X does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not constitute a contribution over the prior art.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the oligonucleotide sequences listed in claims 46, 59, 73, 87, 102, 166, and claim 169 are subject to restriction. The Commissioner has

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partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434).

Applicants are required to elect one sequence from the claims depending on the group elected. Claims 46, 59, 73, 87, 102, and 166 specifically claim oligonucleotide SEQ ID NOS: 2-28, 10-16 and 37 and claim 169 specifically claims oligonucleotide SEQ ID NOS: 1-16 and 18-19, encoding different and distinct oligonucleotides. Although the oligonucleotide sequences claimed each target and modulate expression of antigen presenting cells of foreign DNA or CpG motif(s) containing oligonucleotides derived therefrom, the instant sequences are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct for the following reasons: each sequence has a unique nucleotide sequence, each sequence targets a different and specific region of gene, and each oligonucleotide, upon binding to gene, functionally modulates (increases or decreases) the expression of the gene and to varying degree. Furthermore, a search of more than one (1) of the oligonucleotide sequences claimed in claim presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) oligonucleotide sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) oligonucleotide sequence from claims 46, 59, 73, 87, 102, and 166 or claim 169.

**NOTE:** Should the generic claim in the elected group be allowed, applicants will be allowed to elect nine additional sequences.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kay Pinkney whose telephone number is (703) 305-3553.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, primary examiner, Dave Nguyen can be reached at (703) 305-2024.

If attempts to reach the primary examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Brian Whiteman

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PRIMARY EXAMINER